



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,021	01/30/2004	Robert R. Whittle	5573-115IP7CT7	9712

20792 7590 01/12/2006

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

GRAFFEO, MICHEL

ART UNIT PAPER NUMBER

1614

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/769,021	Applicant(s) WHITTLE ET AL.	
	Examiner Michel Graffeo	Art Unit 1614	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-84 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 65-84 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/20/04; 6/3/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Action

The preliminary Amendment (Filed 20 July 2004) canceled claims 1-64 and presented new claims 65-84. Claims 65-84 are pending and examined.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Information Disclosure Statement

The information disclosure statement filed 20 July 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The foreign and non-patent literature references were not located in the instant file nor any parent file. The IDS has been placed in the application file, but the information referred to therein has not been considered.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Regarding the Norwegian Office Action reference noted in the IDS filed 3 June 2005, the listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 65, 68, 70, 73, 75, 78, 80 and 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "about" in the phrases "about 5mg to about 60mg" (claim 65) and "about 10mg" (claim 68), for example, are relative terms which render the claims indefinite. Since the term "about" is not defined by the claims and the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Because objective standards for the term "about" has not been provided by Applicants, subjective interpretations of these terms would be involved in determining whether or not a particular period of time or dose is included by or excluded from the present claims. It is therefore the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims fail to meet either the tenor or express requirements of 35 U.S.C. §112, second paragraph and are properly rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 65-84 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/32957 to Astra Aktiebolag.

The WO 95/32957 reference teaches the 5-methoxy and 6-methoxy enantiomers of omeprazole (in current claims 65-84; see page 4 lines 15-25) and magnesium cations thereof in an enterically coated capsule form (in current claims 66, 69, 71, 74, 76, 79, 81 and 84; see page 9 lines 8, 17 and 20) for the inhibition of gastric acid secretion (in current claims 65-84; see page 1 lines 10-15) wherein the active agent is present in from .1 to 95% of the dosage unit (in current claims 65, 70, 75 and 80; see page 9 lines 8-10) and for example 50mg (in current claims 68, 73, 78 and 83; see page 18 Table 1) and further wherein the active agent can be either the 5- or 6-methoxy enantiomer or both since they are both made separately and/or able to be separated (see for example page 12 Example 4 wherein the 6-methoxy is made to at least 92% purity).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

Art Unit: 1614

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-68 of U. S. Patent No. 6,369,087 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Regarding the method and process claims of the patent claims, one of ordinary skill in the art would have found a process of making and a process of using the claimed compounds to be obvious since the compositions are the same and would have been used in the processes.

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-12 of U. S. Patent No. 6,262,085 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Regarding the method claims of the patent claims, one of ordinary skill in the art would have found the process of using the claimed compounds

to be obvious since the compositions are the same and would have been used in the method.

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-17 of U. S. Patent No. 6,706,737 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Although the instant application claims a pharmaceutical formulation, such would be obvious in light of the known application for omeprazole.

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-30 of U. S. Patent No. 6,667,321 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Although the instant application claims a pharmaceutical formulation, such would be obvious in light of the known application for omeprazole. Additionally, the composition comprising a cyclodextrin as claimed in the patent would be obvious since cyclodextrins are commonly used as additives in pharmaceutical

preparations (see cyclodextrin. The Hutchinson Encyclopedia, Helicon (2001).

Retrieved 29 December 2005, from xreferplus.

<http://www.xreferplus.com/entry/1079478>).

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-24 of U. S. Patent No. 6,444,689 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Although the instant application claims a pharmaceutical formulation, such would be obvious in light of the known application for omeprazole. Regarding the method claims of the patent claims, one of ordinary skill in the art would have found the process of using the claimed compounds to be obvious since the compositions are the same and would have been used in the method.

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-5 of U. S. Patent No. 6,667,324 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy

enantiomers of omeprazole. Although the instant application claims a pharmaceutical formulation, such would be obvious in light of the known application for omeprazole.

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-45 of U. S. Patent No. 6,653,329 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Although the instant application claims a pharmaceutical formulation, such would be obvious in light of the known application for omeprazole. Regarding the process claims of the patent claims, one of ordinary skill in the art would have found a process of making the claimed compounds to be obvious since the compositions are the same and would have been used in the process.

Claims 65-84 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-101 of copending Application No. 10/855809. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully claimed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant

Art Unit: 1614

application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Regarding the method and process claims of the patent claims, one of ordinary skill in the art would have found a process of making and a process of using the claimed compounds to be obvious since the compositions are the same and would have been used in the processes. Although the instant application does not specifically recite the coordination complex claimed in the reference application, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable notwithstanding the method of identification or condition of the chemical. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present even though the method of identification may be different.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5 January 2006
MG



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600



Bruce M. Kisiluk, Director
Technology Center 1600